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09/344,526	06/24/1999	MARK S. CHEF	A-66828-2 DJ	9163

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04/25/2003

FLEHR HOHBACH TEST ALBRITTON & HERBERT  
SUITE 3400  
FOUR EMBARCADERO CENTER  
SAN FRANCISCO, CA 941114187

EXAMINER

MARSCHER, ARDIN II

ART UNIT	PAPER NUMBER
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1631

27

DATE MAILED: 04/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/344,526

Applicant(s)

CHEE ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 16-20 and 36-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 16-20 is/are allowed.
- 6) ☒ Claim(s) 36-59 is/are rejected.
- 7) ☐ Claim(s) 45-52 and 55-58 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1 ☐ Certified copies of the priority documents have been received.
- 2 ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- 3 ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Applicants' arguments, filed 12/26/02, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### **TITLE**

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title only is directed to decoding methods whereas both decoding methods as well as methods of making a microsphere array are claimed.

### **NEW MATTER**

Claims 36-51 and 54-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Support for newly added claims 36-51 and 54-57 was pointed to by applicants to originally filed claims as well as the specification at pages 10-13. Consideration of these originally filed claims and said pages 10-13 revealed that array compositions are claimed which comprise a substrate with microspheres with first and second subpopulations of bioactive agents without comprising an optical signature. The more generic limitation which is now in claims 36 and 54 directed to the phrase "do not

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comprise a label" as characterizing first and second populations has not been found as filed. This broadening of the negative limitation from and optical signature to a generic "label", or, alternatively, applying this negative limitation to first and second populations, is therefore NEW MATTER. Independent claim 54 and claims dependent either directly or indirectly from claims 36 or 54 also contain this NEW MATTER. This rejection is necessitated by amendment.

### **VAGUENESS AND INDEFINITENESS**

Claim 59 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 59 depends from claim 60, which has never been submitted in the instant application, and therefore is vague and indefinite as to what is meant by said dependence. Clarification via clearer claim wording is requested. This rejection is necessitated by amendment.

### **IMPROPER DEPENDENCE**

Claims 45-51 and 55-57 are objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 36 and 54 require that the microsphere population with subpopulations do not comprise a label. The label, such as a identifier binding ligand of claims 45-51 and 55-57 therefore cite embodiments which are outside of the metes and bounds of claims

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36 or 54 from which they depend and therefore are not further limiting dependent claims as required by 37 CFR § 1.75(c). This objection is necessitated by amendment.

### PROVISIONAL OBVIOUSNESS-TYPE DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 36-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27-39 of copending Application No. 09/748,706 in view of Walt et al. (P/N 6,023,540; already of record).

The instant claims are directed to open claim wording via the "comprising" wording in line 1 of instant claim 36, for example. Thus, methods which add additional steps to those of the instant claims are included. Walt et al. Describes the imaging, via fiber optics, of microsphere arrays as summarized in the abstract, depicted in Figures 5A through 10B, and detailed in columns 3-15 with examples. Thus, the basic decoding method claims of the instant invention are motivated by Walt et al. to also be imaged as

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is well known in the art to result in the claims of copending application serial number 09/748,706.

This is a provisional obviousness-type double patenting rejection.

### INFORMALITIES

The disclosure is objected to because of the following informalities:

Claims 52 and 58 contain internal periods as subpart designations. For example, see claim 52, lines 8 and 9. Such internal periods are improper.

Appropriate correction is required.

Claims 16-20 are allowed.

Applicants' amendment necessitated the new ground(s) of rejection and objection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO

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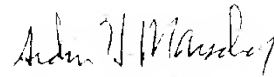
Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

April 25, 2003

A handwritten signature in cursive script, appearing to read "Ardin J. Marschel".